PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Artcle 36 and Rule 70)

Applicant's or agent's file reference PCTA9501-1	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. **PCT/KR2005/000016**	International filing date *(day/month/year)* **05 JANUARY 2005 (05.01.2005)**	Priority date *(day/month/year)* 05 JANUARY 2004 (05.01.2004)

International Patent Classification (IPC) or national classification and IPC

G01N 30/88(2006.01)i

Applicant

Bio-MED Photonics Co., Ltd. et al

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ (sent to the applicant and to the International Bureau) a total of 1 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the report
   - ☐ Box No. II Priority
   - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☒ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
26 OCTOBER 2005 (26.10.2005)	29 MARCH 2006 (29.03.2006)
Name and mailing address of the IPEA/KR Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer PARK, JEONG UNG Telephone No. 82-42-481-8159

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/KR2005/000016

Box No. I Basis of the report

1. With regard to the **language,** this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☒ This report is based on translations from the original language into the following language English, which is the language of a translation furnished for the purposes of:

   ☐ international search (under Rules 12.3 and 23.1(b))
   ☒ publication of the international application (under Rule 12.4)
   ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this reort as "originally filed" and are not annexed to this report):*

   ☐ the international application as originally filed/furnished

   ☒ the description:
   pages 1-110. 112-116 as originally filed/furnished
   pages* 111 received by this Authority on 04 April 2005
   pages* _____ received by this Authority on _____

   ☒ the claims:
   pages 117-129 as originally filed/furnished
   pages* _____ as amended (together with any statment) under Article 19
   pages* _____ received by this Authority on _____
   pages* _____ received by this Authority on _____

   ☒ the drawings:
   pages 1/12-1/12 as originally filed/furnished
   pages* _____ received by this Authority on _____
   pages* _____ received by this Authority on _____

   ☐ the sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:
   ☐ the description, pages _____
   ☐ the claims, Nos. _____
   ☐ the drawings, sheets _____
   ☐ the sequence listing *(specify)* : _____
   ☐ any table(s) related to sequence listing *(specify)* : _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   ☐ the description, pages _____
   ☐ the claims, Nos. _____
   ☐ the drawings, sheets _____
   ☐ the sequence listing *(specify)*: _____
   ☐ any table(s) related to sequence listing *(specify)* : _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has, within the applicable time limti:
   - ☐ restricted the claims
   - ☐ paid additional fees
   - ☐ paid additional fees under protest and, where applicable, the protest fee
   - ☐ paid additional fees under protest but the applicable protest fee was not paid
   - ☐ neither restricted nor paid additional fees.
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is :
   - ☐ complied with.
   - ☐ not complied with for the following reasons:

The common concept linking together the independent Claims 1, 5 & 9 is the following:

including (a) a fluorescently-labeled detector reacts with analyte in liquid sample forming the fluorescently-labeled detector/analyte complex; (b) an unlabeled captor immobilized on the chromatographic medium reacts with the said complex forming the fluorescently-labeled detector/analyte/unlabeled captor triple complex; (c) a fluorescently-labeled reference detector reacts with a reference material in the liquid sample forming a reference complex and the complex further reacts with an unlabeled reference captor forming a reference triple complex; and (d) the amount of analytes is quantified by a laser-induced epifluorescence detection device as the fluorescence intensity of the triple complex of the analyte is being compared with that of the reference complex

Group I : Claims 1-11 The said common concept is apparently neither novel nor inventive. See under Box V.

Group II : Claims 12, dependent on Claim 9. features the window wall having a slope of 20 degree.

Group III : Claims 14 & 15, dependent on Claim 9, feature a time reading window on top plate of the cartridge housing.

The requisite unity of invention (Rule 13.1 PCT) therefore no longer exists between said Groups as far as a single inventive concept within the meaning of Rule 13.2 does not exist between Groups I-III.

4. Consequently, this report has been established in respect of the following parts of the international application :
   - ☐ all parts.
   - ☐ the parts relating to claims Nos.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/KR2005/000016

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	2, 3, 6, 7, 10 & 12-15	YES
	Claims	1, 4, 5, 8, 9 & 11	NO
Inventive step (IS)	Claims	12, 14 & 15	YES
	Claims	1-11 & 13	NO
Industrial applicability (IA)	Claims	1-15	YES
	Claims	none	NO

2. Citations and explanations (Rule 70.7)

Reference is made to the following documents from the International Search Report (ISR):
D1: WO 03062824 A1
D2: US 6136549 A
D3: US 5705338 A

Object of the present invention is to provide a method (Claim 1) and a strip (Claim 5) for the detection of lateral flow assay and a scanner (Claim 9) integrated with a laser-induced epifluorescence detection device.

1. Novelty
(i) regarding Claims 1, 4, 5, 8, 9 & 11
The subject matter of the present invention comprises constituents as recited in Claim 1 featuring a sandwich immunochromatographic method, which includes (a) a fluorescently-labeled detector reacts with analyte in liquid sample forming the fluorescently-labeled detector/analyte complex; (b) an unlabeled captor immobilized on the chromatographic medium reacts with the said complex forming the fluorescently-labeled detector/analyte/unlabeled captor triple complex; (c) a fluorescently-labeled reference detector reacts with a reference material in the liquid sample forming a reference complex and the complex further reacts with an unlabeled reference captor forming a reference triple complex; and (d) the amount of analytes is quantified by a laser-induced epifluorescence detection device as the fluorescence intensity of the triple complex of the analyte is being compared with that of the reference complex. The subject matters of Claims 5 & 9 also feature the aforementioned constituents.

D1 is considered the most relevant state of the art of the present invention in providing a lateral flow quantitative immunochromatography assay method, a strip and a detection means. D1 describes all the constituents of the subject matters of Claims 1, 5 & 9 (see in claims 1,8,18 & 30 of D1). D1 thus appears a novelty-destroying prior art. Claims 4, 8 & 11, which are dependent on Claims 1,5 & 9 respectively, are also disclosed in claims 4, 11 & 21 of D1 and therefore lack novelty.

Consequently, Claims 1, 4, 5, 8, 9 & 11 fail to fulfill the requirements set out in Article 33(2) PCT.

- continued in Supplemental box

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Box No. V

(ii) regarding Claims 2, 3, 6, 7, 10 & 12-15
Claims 3, 7 & 10 limit the unlabeled reference captor of Claims 1,5 & 9 to anti-mouse IgG, whereas use of anti-rabbit IgG is only disclosed in D1.
The dependent Claims 2, 6 & 12-15 impart the additional limitations to the subject matters of Claims 1,5 & 9, which are neither indicated in D1 nor directly inferred from the prior art.

Accordingly, Claims 2, 3, 6, 7, 10 & 12-15 meet the requirements set forth in Article 33(2) PCT.

2. Inventive step
(i) regarding Claims 1, 3-5 & 7-11
If novelty should be disputed based on some minor difference of interpretation, it is pointed out that the subject matter of Claims 1, 4, 5, 8, 9 & 11 would in any case not involve an inventive step. Because only slight modifications in constituents of said claims appear either to come within the scope of the customary practice followed by skilled persons in the art or to be what is easily achievable from the combination of D1 & D2, especially as the advantages thus achieved can readily be foreseen.

D2 discloses a system and a method for a lateral flow assay, wherein a test strip is analyzed by a photometer comprising a light source such as laser diodes and a fluorescence photodetector. Although D2 is directed to a magnetic chromatography assay method, which is alternative to the conventional assay system, D2 describes all the features of the conventional sandwich assay system, which constitute the subject matter of Claims 1, 5 & 9 (see in column 1, line 47 ~ column 5, line 11; column 11, line 23 ~ column 12, line 38; column 13, lines 18 ~ 67; and Figures 3a & 3b).

Regarding Claims 3, 7 & 10, it is believed that use of anti-mouse IgG as either captor or detector falls within the customary practice in the art and is thus obvious to a skilled person in the art. Furthermore, it is easily derivable from the combination of D1 & D2.

Therefore, Claims 1, 3-5 & 7-11 fail to fulfill the requirements set out in Article 33(3) PCT for the lack of inventive step.

(ii) regarding Claims 2, 6 & 13
Claims 2, 6 & 13 add to subject matter of Claims 1, 5 & 9, respectively, an immobilized Ag (Which is unclear but interpreted as antigen or analyte in this report) line, with which Ag or a detector reacts, taking into account the Hook effect. That is also considered a problem to be solved of D3. D3 indicates that the second zone containing an analyte derivative traps unreacted labeled specific binder only, and it thus corresponds to the Ag line of the present claims (see column 3, line 55 ~ column 4, line 19 and claims 6 & 7 in D3). Therefore, it is obvious to a person skilled in the art to arrive at the claimed invention through combining what D1 & D3 teach without exercising an inventive step. The advantage thus achieved is also foreseen.

Accordingly, Claims 2, 6 & 13 do not meet the criteria set forth in Article 33(3) PCT.

- continued in Supplemental box

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:

Box V & Supplemental box

(iii) regarding Claims 12, 14 & 15
Claim 12 is about the scanner featuring the window wall having a slope of 20 degree.

Claims 14 & 15 are about the scanner featuring a time reading window on top plate of the cartridge housing.
The technical features are neither indicated nor suggested in prior art documents. It is unlikely to arrive at the claimed inventions even by combination of teachings from prior art unless exercising an inventive step. Advantages thus achieved in the present claims such as decreasing noise and variations in accuracy are considered unforseen over prior art.

Therefore, Claims 12, 14 & 15 meet the criteria set forth in Article 33(3) PCT.

3. Industrial applicability

Object of Claims 1-15 is to provide a method and a strip for the detection of lateral flow assay and a scanner, which are considered industrial applicable. Consequently, Claims 1-15 meet the requirements of Article 33(4) PCT.